Reply to Office Action of January 16, 2009

#### **AMENDMENTS**

Claims 1-6 and 8-25 are pending.

Claims 4 and 15 have been amended.

Claims 18-25 have been added.

Claims 1-3, 5, 8-9, 11, and 13 have been withdrawn.

Claim 7 has been canceled.

Support for the amendments is found in the claims and specification (e.g., page 3, lines 13-27; page 4, lines 1-4; page 5, lines 15-21; page 6, lines 9-14; page 11, third full paragraph; Examples 1-2, fig. 1; Example 3; Example 5), as originally filed.

No new matter is believed to have been added.

### REMARKS AND REQUEST FOR RECONSIDERAITON

Applicants wish to thank the Examiner for a discussion on March 5, 2009. The species election requirement was discussed. Further, the undersigned Applicants' representative explained that agar-agar is generally produced from small red algae belonging to the order *Gelidiales* which is different form the order *Ceramiales* to which *Digenea simplex* belongs. The rejection over Lopez describing a soap composition comprising 0.1-25 wt. %. of agar-agar was discussed. The Examiner was willing to reconsider the prior art rejection in view of the proposed amendments and arguments.

Aging of cells of the skin causes changes in appearance, including formation of wrinkles, sagging of the skin, and loss of the skin elasticity (page 1 of the specification). The claimed method is based on the finding of the relation between the force generated in skin fibroblasts, i.e. non-muscle cells, and aging. The inventors have found that the force generated by skin fibroblasts (i.e., non-muscle cells) is reduced with aging, and that the expression of an enzyme which phosphorylates myosin light-chain, i.e. Rho kinase or myosin light-chain kinase, is reduced in aged skin fibroblasts. The present inventors have also found

that a substance capable of enhancing the expression level of such an enzyme can prevent aging of the skin such as sagging of the skin, loss of skin elasticity, or wrinkle formation, or improve the skin.

The claimed method is directed to treating aging of the skin which has wrinkles, is sagging, and/or has a loss of the skin elasticity, comprising contacting the skin of a subject in need of a treatment with a skin treating agent, thereby increasing an expression level of Rho kinase or myosin light-chain kinase in the skin and, thus treating or improving a condition of the aging skin of the subject, wherein the agent comprises a substance capable of increasing an expression level of Rho kinase or myosin light-chain kinase, wherein the substance capable of enhancing the expression level of Rho kinase or myosin light-chain kinase is a plant, a part of a plant, an extract of a plant, an extract of a plant or a combination thereof, and said plant is *Digeneasimplex* enhancing the expression level of Rho kinase or myosin light-chain kinase.

Claims 4, 6, 10, 12, and 14-17 are rejected under 35 U.S.C. 103(a) over Lopes, US 5,942,478, and the Sigma Aldrich Catalogue (1996). The rejection is traversed because the combination of the references does not describe or suggest:

- (1) treating of the skin which has wrinkles, is sagging, and/or has a loss of the skin elasticity, comprising contacting the skin of a subject in need of a treatment with a skin treating agent comprising an extract of *Digeneasimplex* enhancing the expression level of Rho kinase or myosin light-chain kinase (a sin claims 4 and 15);
  - (2) "agar-agar" is different from Digene simplex;
- (3) a treating agent capable of increasing the force generated by skin non-muscular cells, wherein the skin non-muscular cells are skin fibroblasts (as in claims 19-20 and 22-23);
- (4) an amount of the extract as reduced to dry weight is 0.00001% wt. to 0.01% (or to 0.002 %) based on the total amount of said agent (as in claims 24-25).

- (5) In addition, one would not have been motivated to select a subject in need of a treatment of wrinkles, sagging skin, and/or a loss of the skin elasticity, and to apply the Lopes soap with a reasonable expectation of increasing the force generated by skin non-muscular cells (increasing the level of Rho kinase and/or myosin light-chain kinase) and treating or improving wrinkles, sagging skin, and/or a loss of the skin elasticity.
- (1) The combination of the references does not describe or suggest treating of the skin which has wrinkles, is sagging, and/or has a loss of the skin elasticity, comprising contacting the skin of a subject in need of a treatment with a skin treating agent comprising an extract of Digeneasimplex enhancing the expression level of Rho kinase or myosin light-chain kinase.

Lopes describes a soap composition comprising 0.1-25 wt. %. of agar-agar, wherein the agar-agar is added as a skin-lubricating and skin-protecting agent (abstract, col. 4, line 64 to col. 5, line8; col.2, lines 13-26). The Sigma Aldrich Catalogue describes that agar-agar has a synonym *Digenea simplex* mucilage (page 1).

- (a) The claimed invention is a *method* of treating/improving the aging skin, <u>not</u> a composition. Further, Lopes uses agar-agar in a microbicidal and sanitizing soap composition as a lubricant and a skin-protecting agent.
- (b) Lopes does not describe that a soap composition and/or lubricant and a skin-protecting ingredients of the soap can be used for treating aging skin (e.g., wrinkles, sagging of the skin, and/or a loss of the skin elasticity).

Lopes does not describe a treating agent capable of increasing the force generated by skin non-muscular cells, wherein the skin non-muscular cells are skin fibroblasts (as in claims 19-20 and 22-23).

(c) Lopes does not describe selecting a subject in need of a treatment and applying the claimed agent for treating aging skin.

- (d) Even if the lubricant and skin-protecting ingredients of the Lopes soap can lubricate the skin and, possibly, improve the skin, the effect is expected to be cosmetic. Lopes does not describe that the lubricant and a skin-protecting ingredients of a soap can treat (and are intended to treat) the aging skin which has wrinkles, is sagging, and/or lost elasticity.
- (e) There is insufficient <u>nexus</u> between a cosmetic effect (lubricating the skin) and a therapeutic effect (treating the aging skin). The need for lubricating may be caused by ingredients used in a soap to improve feel after using the soap (e.g., because of other soap components cause dry feeling), while the claimed method is directed to treating a subject in need of improving wrinkles, is sagging, and/or lost elasticity.
- (f) A soap of Lopez is a washable composition providing microbicidal and sanitizing effects, while in the claimed method, the skin treating agents are applied to the skin for treatment (i.e., not washable).

#### (2) "Agar-agar" is different from Digene simplex

The toxonomy pages attached with this paper show that agar is generally produced from small red algae belonging to the order *Gelidiales* which is different form the order *Ceramiales* to which *Digenea simplex* belongs. The *Gelidiales* species are important sources of high quality agar (see the attached pages: http://tolweb.org.Gelidiales/21751 (3 pages; Wikipedia at http://en.wikipedia.org/wiki/Gelidiales (one page);

http://en.wikipedia.org/wiki/Gelidium (one page);

http://www.algaebase.org/browse/toxonomy/?id=8186 (one page);

http://www.algaebase.org/browse/toxonomy/?id=5217 (one page);

http://www.anbg.gov.au/amanisearch (one page)).

(3) The references do not describe a treating agent capable of increasing the force generated by skin non-muscular cells, wherein the skin non-muscular cells are skin fibroblasts (as in claims 19-20 and 22-23).

Lopes describes a soap composition comprising agar-agar but does not describe that the soap or agar-agar is capable of increasing the force generated by skin non-muscular cells, wherein the skin non-muscular cells are skin fibroblasts.

(4) The references do not describe an amount of the extract as reduced to dry weight is 0.00001% wt. to 0.01% (or to 0.002 %) based on the total amount of said agent (as in claims 24-25).

Lopes describes a soap composition comprising 0.1-25 wt. %. of agar-agar (col. 2, lines 13-26). The references do not describe an amount of the extract as reduced to dry weight is 0.00001% wt. to 0.01% (or to 0.002 %) based on the total amount of said agent (as in claims 24-25).

(5) One would not have been motivated to select a subject in need of a treatment of wrinkles, sagging skin, and/or a loss of the skin elasticity, and to apply the Lopes soap with a reasonable expectation of increasing the force generated by skin non-muscular cells and treating or improving wrinkles, sagging skin, and/or a loss of the skin elasticity.

Lopes describes a soap composition comprising agar-agar, wherein agar-agar is added as a skin-lubricating and skin-protecting agent (abstract, col. 4, line 64 to col. 5, line8; col.2, lines 13-26).

One would not have been motivated to select a subject in need of a treatment of wrinkles, sagging skin, and/or a loss of the skin elasticity, and to apply the Lopes soap with a reasonable expectation of (a) treating or improving wrinkles, sagging skin, and/or a loss of the skin elasticity, and/or (b) increasing the force generated by skin non-muscular cells because (i) there is insufficient nexus between a cosmetic effect (lubricating the skin) and a therapeutic effect (treating the aging skin), (ii) Lopez's washable composition provides microbicidal and sanitizing effects, while in the claimed method, the skin treating agents are applied to the skin for treatment, and (iii) Lopes does not describe selecting a subject in need of a treatment and applying the claimed agent for treating aging skin.

Application No. 10/791,753

Reply to Office Action of January 16, 2009

Thus Lopez and the Sigma Aldrich Catalogue do not make the claimed method

obvious.

This application presents allowable subject matter, and the Examiner is kindly

requested to pass it to issue.

Should the Examiner have any questions regarding the claims or otherwise wish to

discuss this case, he/she is kindly invited to contact Applicants' below-signed representative,

who would be happy to provide any assistance deemed necessary in speeding this application

to allowance.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,

M. Wille

MAIER & NEUSTADT, P.C.

Norman F. Oblon

Customer Number

22850

Tel: (703) 413-3000 Fax: (703) 413 -2220

(OSMMN 08/07)

Marina I. Miller, Ph.D. Attorney of Record

Registration No. 59,091

12

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183



123,403 species and infraspecific names are in the database, 6.710 images, 42,485 bibliographic items, 46,604 distributional records.

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Brachiomonas submarina Bohlin.

Family: Gelidiaceae

Gelidiales

Gelidiaceae

Family

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Or you can browse though the hierarchy by clicking on the names on the right and drilling down. At each level the numbers of current species are given for each taxon. Only currently accepted names are included. Should you find any errors, please click on the little envelope icon, and you can send me an email via the site.

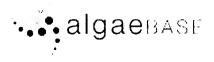
In order to make calculations of the numbers of species of living algae, note that 58 or so species of flowering plants (seagrasses) are included for the present (under the Phylum Magnoliophyta), and 1644 fossil algae, mainly calcium- and silica- secreting forms.

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Higher Taxo	nomy						
Rank	Name	Authority	# Species				
Empire	Eukaryota	Chatton	24,552	±	۳	$\succeq$	•
Kingdom	Plantae	Haeckel	12,258	<b>±</b>	۳	$\odot$	
Subkingdom	Biliphyta	Cavalier-Smith	6,094	ψį		ت	
Phylum	Rhodophyta	Wettstein	6,089	4	٣	$\overline{\Sigma}$	
Subphylum	Rhodophytina	H.S. Yoon, K.M. Müller, R.G. Sheath, F.D. Ott & D. Bhattacharya	6,089	Ė	ث	₩	
Class	Florideophyceae	Cronquist	5,855	4	()	$\subseteq$	
Subclass	Rhodymeniophycidae	G.W. Saunders et Hommersand	4,961	÷,	٣	$\subseteq$	

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Subordinate taxa							
Rank	Name	Authority	# Species				
Genus	Acanthopeltis	Okamura	2	Œ	ث	$\overline{\Sigma}$	
Genus	Beckerella	Kylin	6	<b>(</b>	ت	$\overline{\Sigma}$	
Genus	Capreolia	Guiry & Womersley	1	4	ت	$\succeq$	
Genus	Gelidium	J.V. Lamouroux	116	<b>±</b>	ت	ك	
Genus	Pterocladiella	Santelices & Hommersand	14	4	ت	$\succeq$	
Genus	Ptilophora	Kützing	16	4	ت	ت	
Genus	Yatabella	Okamura	1	4	ت	$\cong$	
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### Taxonomy Browser >>

123,403 species and infraspecific names are in the database, 6.710 images, 42,185 bibliographic items, 146,604 distributional records.

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You can search for a particular taxon (e.g. "Zygnematales"; "Zygnemataceae"; "Zygnema") at any level by entering the **exact** name in the field above.

Or you can browse though the hierarchy by clicking on the names on the right and drilling down. At each level the numbers of current species are given for each taxon. Only currently accepted names are included. Should you find any errors, please click on the little envelope icon, and you can send me an email via the site.

In order to make calculations of the numbers of species of living algae, note that 58 or so species of flowering plants (seagrasses) are included for the present (under the Phylum Magnoliophyta), and 1644 fossil algae, mainly calcium- and silica- secreting forms.

			Genus:	Digenea
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Higher Taxo	nomv			Start	Ove	(4)
Rank	Name	Authority	# Species			
Empire	Eukaryota	Chatton	24,552	4	ت	$\leq$
Kingdom	Plantae	Haeckel	12,258	ė,	٣	$\cong$
Subkingdom	Biliphyta	Cavalier-Smith	6,094	<b>(±</b> )		$\cong$
Phylum	Rhodophyta	Wettstein	6,089	÷,	٣	$\overline{\mathbf{Z}}$
Subphylum	Rhodophytina	H.S. Yoon, K.M. Müller, R.G. Sheath, F.D. Ott & D. Bhattacharya	6,089	<b>±</b>	۵	Ÿ
Class	Florideophyceae	Cronquist	5,855	4	<u>(m)</u>	$ \mathbf{\mathbb{Y}} $
Subclass	Rhodymeniophycidae	G.W. Saunders et Hommersand	4,961	<b>(±)</b>	۵	$\subseteq$
Order	Ceramiales	Oltmannş	2,396	$\oplus$	ت	$\boxtimes$
Family	Rhodomelaceae	J.E. Areschoug	927	<b>(±)</b>	(")	$\subseteq$
Genus	Digenea	C. Agardh	2	÷,	(")	$\succeq$

Subordinate taxa						
Rank	Name	Authority	# Species			
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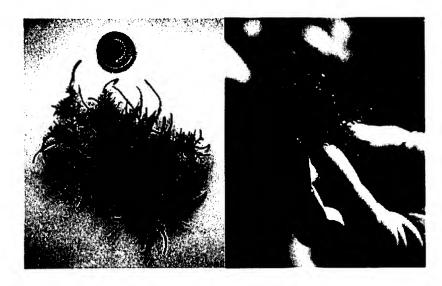
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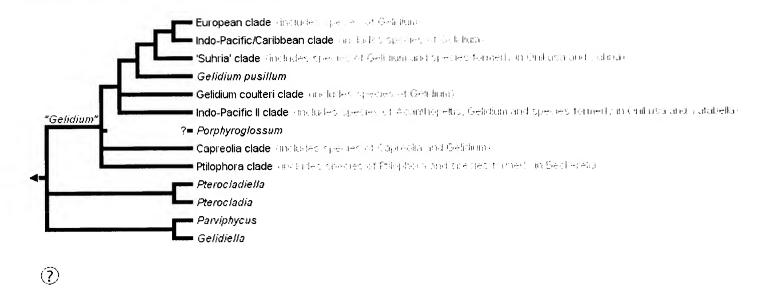
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#### Gelidiales

#### D. Wilson Freshwater







Tree based on Freshwater et al. 1995, Freshwater and Bailey 1998, Shimada et al. 1999, Rico et al. 2002, and Freshwater unpublished. Clade labels refer to the type of morphology and development of the female reproductive system and carposporophyte as discussed in Bailey and Freshwater (1997).

Containing group. Florideophyceae

#### Introduction

The Gelidiales is a relatively small order of red algae containing ca. 130-140 species placed in ten recognized genera. Many gelidialean species are economically important as sources of high quality agars. The order is defined by the unique set of characters listed below.

#### Characteristics

Species within the Gelidiales share a unique set of characters that make this a well-defined order of red algae. These characters include:

Gelidiales Page 2 of 3

- a triphasic life history with isomorphic gameto- and tetrasporophytes
- agar as a cell wall component
- pit plugs with a single cap layer
- a special "Gelidium-type" spore germination pattern
- uniaxial filaments that branch in three planes forming a pseudoparenchyma
- intercalary carpogonia that after fertilization produce gonimoblasts that connect to nutritive cells
- transversely divided spermatangia

#### Discussion of Phylogenetic Relationships

Four major lineages have been identified by molecular analyses of taxa within the Gelidiales (Bailey and Freshwater 1997, Freshwater et al. 1995, Freshwater and Bailey 1998, Shimada et al. 1999). The morphology and development of the female reproductive system and carposporophyte may also define these lineages (Bailey and Freshwater 1997, Hommersand and Fredericq 1988, 1996, Santelices and Hommersand 1997). Three of the lineages are equivalent to the monophyletic genera Pterocladiella, Pterocladia, and Gelidiella. The fourth lineage defines a large clade that includes species of Acanthopeltis, Capreolia, Gelidium, Porphyroglossum, and Ptilophora. As noted on the Gelidiales tree above, species representing four other genera are also resolved within this lineage, but recent studies have synonimized these with currently recognized genera (Norris 1987, Shimada et al. 1999, Tronchin et al. 2003a). Analyses of nuclear-encoded 285 rRNA gene sequence data (Freshwater and Bailey 1998) and a combined four gene data set (Freshwater unpublished) have resolved Pterocladiella and Pterocladiella as sister taxa, but relationships among the four major lineages can not currently be determined based upon non-molecular characters. The morphology and development of the Gelidiella female reproductive system and carposporophyte is unknown, and therefore the associated characters, which define the other three lineages, cannot be used to determine phylogenetic relationships among them.

Most species included in molecular analyses have been resolved within the "Gelidium" lineage. As noted above, this lineage includes species of not only Gelidium, but four other currently recognized genera as well. Molecular analyses identify at least eight clades within this lineage that have been referred to as "species complexes" or "species clades" (Freshwater and Rueness 1994, Freshwater et al. 1995, Shimada et al. 1999, Tronchin et al. 2003a). In contrast to the four major gelidialean lineages, morphological and/or developmental synapomorphies are unverified for all but the Ptilophora clade. The vegetative thalli of all species in the Ptilophora clade are constructed of four tissue layers composed of different cell types (Tronchin et al. 2003b). Santelices (1999) has defined a number of characters associated with the development of the cystocarp that may be synapomorphies for species clades within the "Gelidium" lineage. Further study is needed to determine if these or other characters will be useful for phylogenetic analyses.

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#### Title Illustrations



Scientific Name Gelidiella acerosa

Location collected at Cahuita on the Caribbean coast of Costa Rica

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Scientific Name Gelidium arbuscula Location collected on the no

collected on the north coast of Gran Canaria, Canary Islands

Acknowledgements Hand model courtesy of Jose Rico



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# Gelidium

From Wikipedia, the free encyclopedia

**Gelidium** is a small genus of red algae containing 114 species. Many of the algae in this genus are used to make agar.

# **Species**

# Gelidium

### Scientific classification

Domain: Eukaryota

(unranked): Archaeplastida

Phylum: Rhodophyta

Class: Florideophyceae

Order: Gelidiales

Genus: Gelidium

**Species** 

See species section

# **Gelidiales**

**External links** 

From Wikipedia, the free encyclopedia

The Gelidiales is a small order of red algae containing ten genera, and approximately 130-140 species, many of which are used to make agar.

### Gelidiales Scientific classification

Domain: Eukaryota

(unranked): Archaeplastida

Phylum: Rhodophyta

Florideophyceae Class:

Order: Gelidiales

**Families** 

This Alga-related article is a stub. You can help Wikipedia by expanding it

(http://en.wikipedia.org/w/index.php?title=Gelidiales&action=edit).

• Tree of Life: Gelidiales (http://tolweb.org/Gelidiales/21751)

Retrieved from "http://en.wikipedia.org/wiki/Gelidiales"

Categories: Red algae | Algae stubs

Gelidiaceae Gelidiellaceae

Pterocladiaceae

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Taxonomy Details Page 1 of 1





Australian Marine Algal Name Index

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## **Taxonomy**

Macro-algae

Division: Rhodophyta
Subdivision: Eurhodophytina
Class: Florideophyceae

Subclass: Rhodymeniophycidae

Order: Ceramiales

Family: Rhodomelaceae

Genus: Digenea

**Currently Accepted Species Name** 

Species: Digenea simplex (Wulfen) C.Agardh 1822: 389

Agardh CA (1822) Species algarum . Vol. 1, part 2, fasc. 1 Berling: Lund. pages v-vi + 169-398.

Further reference information

Basionym

Species: Conferva simplex Wulfen 1803: 17

Wulfen FX (1803) Cyptogama aquatica Archiv fur die Botanik 3: pages 1-64, pl. 1

Further reference information

#### **Illegitimate Name**

Species: Digenea wulfenii Kütz. nom. illeg. 1843: 433

Kuetzing FT (1843) Phycologia generalis . F.A. Brockhaus: Leipzig. pages i-xxxii + 1-458, pl. 1-80.

Further reference information

Note: Kuetzing changed the species epithet unnecessarily.

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